THE ETHICAL OPHTHALMOLOGIST

Research ● New Technology ● Collegiality

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(Material adapted from the *The Ethical Ophthalmologist: A Primer,* a text by the Ethics Committee of the American Academy of Ophthalmology.)

Summary: This course covers ethical issues and concerns and their impact on every day decision-making in ophthalmology. The case study approach, with questions and discussion, provides an opportunity to recognize and analyze ethical dilemmas. These learning activities will also heighten awareness of ethical and moral principles in certain aspects of contemporary medical practice such as research and new technology, delegated services, commercial relationships, compensation, and advertising.

Audience: Ophthalmologists, eye care professionals, and ethicists.

Objectives: After completing The Ethical Ophthalmologist: Course III, you should be able to explain the ethical approach you would take in handling the delegation of non-physician services, the dilemmas posed by research and new technology, and issues of collegiality.

Accreditation: The American Academy of Ophthalmology is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Designation Statement: The American Academy of Ophthalmology designates this educational activity for a maximum of one *AMA PRA Category 1 Credit*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

CME: CME credit is available to all users of this educational activity.

Financial Disclosure: The authors acknowledge no financial interest in the subject matter of this course.

Editor's Note: This text is for educational purposes. It is intended to promote discussion and understanding of the ethical issues facing ophthalmologists. This text does not interpret, modify, amend, or supplement the Code of Ethics of the American Academy of Ophthalmology or any of the Advisory Opinions. All names used in the case studies in this text are fictitious, and have no intended relationship to any persons involved in any past or present ethics matter considered by the Academy's Ethics Committee. Any similarities in the names chosen in the case studies to those of actual ophthalmologists or other persons are entirely coincidental.

Finally, although this project was undertaken with the full support and encouragement of the Academy's Board of Trustees, and was completed with the invaluable assistance of the Academy staff and resources, the text itself is the sole product of, and responsibility of, the individual authors and editors.

INTRODUCTION

Ethics in Ophthalmology? "Of course," you might respond. "Ethical crises can arise in any medical specialty. When they do, we make a conscientious effort to address and resolve them, and then return to our primary responsibility, managing the medical problems at hand." The fact is, ethical concerns are not limited to occasional events we might describe as crises. Rather, they permeate even the simplest decisions we make in relation to our patients. Ethical principles and behavior are an integral part of the practice of medicine. For this reason, the ability to recognize and act on ethical issues is an essential qualification of the competent physician, the competent ophthalmologist, and the whole person.

Imagine, for example, that several patients have contacted you recently for a second opinion on the urgent need for cataract extraction. Each surgery was recommended by a particular ophthalmologist in your community. In each case, you find that new glasses improve the patient's vision to a level entirely satisfactory to the patient. What do you tell the patients? Do you have a larger responsibility to protect other patients from unnecessary surgery? What obligation do you owe the other ophthalmologist?

Another example: a 3-year-old boy with developmental delay and cerebral palsy is brought to you for evaluation of esotropia and moderate hyperopia by concerned parents. The parents tell you that the child was recently examined by another eyecare professional who told them it was impossible to determine whether the child could see, and that the correction of strabismus with glasses and surgery was not advised because "it would really be just for cosmetic purposes and wouldn't last." What do you tell the parents?

Neither of these two examples constitutes a life and death matter, and neither could be considered an ethical crisis. Yet, such situations raise a range of issues that test the ophthalmologist's knowledge, understanding, sensitivity, compassion, and moral judgment - in brief, his or her ethical awareness and behavior. Similar predicaments, some more mundane, some more dramatic, are part of the practice of medicine. Yet practical guidance in how to deal with these events has largely escaped attention in most of the books that fill our professional libraries. There is no *Duke Elder* or *Duane's* textbook to provide instruction. We may recognize the ethical competence of our physician role models and we can learn from them, but a specific presentation of ethical issues that impinge on the practice of ophthalmology could prove a useful adjunct. Such a guide could serve to increase our moral awareness and competence in managing the obligations of our profession. These courses attempt to fill that need.

It should be clear that this is not a "cookbook" or "how-to" handbook for ethical conduct. It is only a guide. You will note that there are questions related to the various case studies presented. These are offered to illustrate the fact that, in many instances, no single response is the only correct course of action. Conflicting ethical concerns may be present; alternatives exist, and the physician must consider the choices based on the ethical principles that pertain to the conditions of the situation described. Hopefully, this activity can aid the teaching and learning process in which physicians become better healers: healers of their patients, their communities, and themselves.

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RESEARCH
Ophthalmologists participate in many forms of research, ranging from laboratory studies of animal models of human disease to clinical trials of new ophthalmic drugs and procedures. Even the practicing ophthalmologist who denies active involvement in research has occasion to evaluate emerging surgical techniques, new medications, and novel diagnostic methods as part of his or her daily activities. Although few would argue against the potential benefits and vital importance of research, serious problems may be encountered in such pursuits, due not to medical errors but to a failure to understand correlative issues unique to research. This case study is designed to address the ethical issues that are inherent in the performance of research.

Case Study
Case #1
An elderly woman comes to an ophthalmic clinic in hopes that her vision can be improved. She is examined by a second-year resident. She had been told elsewhere that her retina had "deteriorated", information that came as no surprise to her since other family members have a similar condition. The patient is eager to undergo any treatment if it offers the hope of improving her vision. The resident examines the patient, noting visual acuity in the range of 20/200 in each eye, and observes findings consistent with exudative macular degeneration. The resident believes that the patient is a candidate for intravitreal treatment with an

approved VEGF-inhibitor, and wonders whether she might also be a candidate for treatment with a novel intravitreal medication that was recently presented at a local meeting by a senior ophthalmologist. The resident contacts the senior ophthalmologist, who states that he has been very encouraged by the results obtained in the several patients treated with the novel study medication. In fact, one of the patients was so pleased that, through her business connections, she facilitated a publicity release regarding the efficacy of the treatment. The ophthalmologist delights in the resident's interest and offers the opportunity to participate in the ongoing research project. The resident, who has already begun pursuing a vitreoretinal fellowship, readily accepts the offer. The resident discusses what is known about the new treatment with the patient, who enthusiastically volunteers to participate in the research program. As a research subject, the patient will now receive free medical care for her condition.

Thought Questions

A. What are the similarities and differences between the conduct of research and the performance of direct patient care?

B. How might the individual motives or concerns of the patient, the resident, and the senior ophthalmologist influence the outcome of this clinical trial? Could the design of the research project be altered to reduce these biases?

C. What impact might errors in the research program have on patient care?

Discussion

This case illustrates a major force that drives many research endeavors: the patient with a medical conditon for which present treatment strategies are able to achieve only modest gains. One could argue that if available treatment strategies fail, the appropriate role of a supportive ophthalmologist is to acknowledge the disease entity and help the patient deal realistically with the limitations imposed by the disease. Further assistance could be offered in terms of low-vision aids, resources for impaired persons, and education as to the natural history of the specific disease process. The researcher, on the other hand, is a bit of a dreamer and is not content to accept the status quo, thinking and hoping that amelioration or even a cure might be found. While commendable, the optimism and enthusiasm expressed by the resident in this case pose a potential problem in the accurate evaluation of the proposed treatment, particularly since this resident may lack the skills to critically evaluate the study design and early patient outcomes. Without such skills, the resident may not recognize the clear biases of both the patient and the investigators.

The patient’s hopes of regaining any part of her lost vision may result in a subjective improvement in function following treatment with the experimental medication, even though her measured visual acuity may not have changed. Since the resident noted a visual acuity in the “range” of 20/200 in the initial examination, it is even possible that testing after treatment may appear to reveal improved acuity. The free care provided to the patient may also influence her subjective report of the outcome.

For peripheral reasons, the resident and senior ophthalmologist have vested interests in the success of the experimental medication, interests that may influence the accuracy of observations and the interpretation of results. The ophthalmologist has already obtained “encouraging” results in other patients and publicity over apparent success is a validation hard to ignore, particularly if the senior ophthalmologist’s practice has notably increased its volume. The resident, of course, is anxious to please the senior ophthalmologist, and senses that success in this research project can do no harm to the resident’s prospects for a fellowship or other career advancement.

In brief, the outcome of the experimental treatment in this case, successful or not, will be suspect because the resident and the senior ophthalmologist have failed to control for the biases of both the patient and investigators and have disregarded the rigorous requirements of a research study. A basic ophthalmic examination and measurement of visual acuity before and after treatment are not sufficient observations to evaluate the efficacy of the medication.

Research studies are generally collaborative efforts, requiring the expertise of various individuals and diverse disciplines to design and conduct a meaningful program and to evaluate results.

In this instance, the resident and the senior ophthalmologist erred in not consulting with others in the clinic who were more experienced in research study design before undertaking even a limited trial of the experimental medication. Were this done, the resident, no doubt, would have been advised to perform a more intensive initial assessment of the patient's visual function and to schedule repeated examinations according to a specific predetermined protocol during and following the course of treatment. Evaluations by two different physicians would have been recommended to control for inter-observer variation. The patient would have been counseled that the medication was experimental, with only preliminary evidence to suggest that it might help; she should have been informed of all possible treatment outcomes, including the possibility that she may experience no change in her condition. Finally, the resident would have been advised to review available information on safety of the medication and to monitor the patient during treatment in order to reduce the risk of adverse reactions.

Additionally, the objectives and protocol for the research project should have undergone the rigorous review of an affiliated institutional review board prior to the initiation of patient recruitment. To obtain a truly meaningful evaluation of the medication, multiple patients with similar clinical features would have to be included in the study, half to receive the experimental preparation, and half to receive a placebo, to control for both patient and physician biases. Ideally, the study would be double-blind, wherein neither the patient nor the examining ophthalmologist knows whether the patient receives the active medication.

These suggestions are technical considerations overlooked in the treatment of the patient and in the evaluation of the experimental medication. The greater error was the failure of the resident and the senior ophthalmologist to recognize and deal with the ethical issues surrounding this new treatment. The resident failed to recognize the difference between the welfare of the patient and the advancement of science. The resident also allowed personal interests and those of the senior ophthalmologist to threaten the validity of the study, thus failing ethical obligations both to the patient and to the scientific community.

Analysis of Principles

The Scientific Process

The fundamental ethical issue in research is the obligation to conduct an investigation competently and accurately. In reality, total freedom from bias is quite difficult because each of us carries expectations that inevitably influence what we observe. Nonetheless, such biases must be acknowledged, and to the extent possible, excluded by means of the research design.

Communication and Reporting

Another ethical issue associated with research relates to communication both in the initiation of research projects and in the reporting of results. On conclusion of an investigation, the researcher bears an ethical responsibility to report the date and results within appropriate avenues of communication. Although the temptation exists to contact the public media directly with promising preliminary results, the more correct and responsible approach is to present such information at recognized meetings of peers, or to publish the results in a scientific journal refereed by other knowledgeable investigators in the field.

Conflict of Interest

Conflicts of interest may exist beyond financial rewards. The "publish or perish" mentality at some academic centers may drive projects to a premature conclusion or create even more serious influences on a researcher. An insatiable desire for fame or "being first" to discover has had a negative impact on more than one academic ophthalmologist, and more tragically on patients and students in his/her trust.

Informed Consent

Participation in a research project requires the patient to sign a special informed consent statement. The purpose of the document, which is based on principles established as a result

of the Nuremberg trials following World War II, is to assure that the subject understands fully the purpose of the study, the medical procedures to be performed, and their attendant risks. Another purpose of the statement is to confirm that the patient has volunteered to participate freely and without coercion, and that the patient is aware that he or she may elect at any time during the course of the experiment to withdraw from further participation. If the treatments are to be randomized or administered in a double-blind manner, the patient must understand the purpose of the experimental design. Finally, any financial interests of the investigators must be disclosed.

Funding of Research
A prudent investigator must take added precautions to ensure that, despite potential conflict of interest, funding does not interfere with the scientific process nor with the reporting of results. The investigator must also be prepared to resist outside efforts to influence the research program and be willing to acknowledge the source of the financial support in subsequent publications. A patient who participates in a research project may be treated at a reduced charge or for no fee. In some cases, the patient may receive a stipend or travel expenses. In these cases, the investigator must acknowledge such financial considerations, particularly if the study involves subjective measurements.

NEW TECHNOLOGY
Limitations of current therapies coupled with creative imaginations lead practitioners to evolve new therapies with which to help patients. By definition, innovative therapies are not the standard of practice. A practitioner with an unorthodox outlook must be careful to remain objective and demonstrate that the new idea serves the patient.

Case #2
An ophthalmologist in your vicinity, Dr. Lowe, has been wrestling with the problem of low tension glaucoma for several years. He has become convinced that when the pressure falls to low levels, the circulation feeding the nerve fiber layer on the nerve head requires a certain amount of tamponade effect in order to keep the vessels from rupture with consequent infarction of the nerve fiber layer. Following this theory, he has begun to advocate heavy repeated laser trabeculoplasty in order to raise the intraocular pressure to what he considers a safe level, about 18 - 22 mm Hg. He is convinced that his results support his theory. He responds with disdain to medical or surgical therapy to lower IOP when he believes that the pressure was already too low.

Dr. Lowe presents his theories readily at any time and place he can get an audience, including nonprofessional settings like radio talk shows and civic clubs. Because of his passionate belief, he is an entertaining if somewhat self-righteous speaker. As a result of his high public profile, his practice has grown rapidly. This morning you may have heard Dr. Lowe on the radio in an interview. He was telling the interviewer that most ophthalmologists think glaucoma is only a matter of high pressure in the eye. In fact, he says, about as many people have glaucoma with normal pressures as with high pressures. He was encouraging patients with normal pressures to call his office or the office of another "aware" ophthalmologist for a glaucoma check. He further encouraged anyone with signs of glaucoma with low pressures to contact him regarding his study using laser treatment to increase the pressure to a higher level.

Case #3
Dr. Sand has been interested in refractive surgery for some time, but for various reasons he does not wish to learn conventional refractive surgery or to try marketing the procedure in his area. Being innovative and imaginative, he has combined his considerable knowledge of corneal surgery with his experience in making contact lenses to invent a process for grinding down the cornea with a diamond burr to reshape the cornea. As he believes that he is obtaining superior results with his new refractive surgery technique, he has patented the process and the machine used in the surgery, and is now selling the machine and an instruction course as a package to interested colleagues.

Thought Questions

A. How should an ophthalmologist manage clinical situations for which he or she thinks the standard therapies are suspect?

B. Should the practitioner continue with the standard therapies, believing that his or her own approach is better or more sound?

C. If you believe that an established therapy is antiquated or even harmful, should you take your case to the public if the professional channels offer resistance?

D. Is there a corresponding duty to protect the public from new technologies with which you disagree?

E. Should a new technology be used as a marketing device in a competitive practice climate?

F. What do you tell a patient who asks you about new or unconventional ideas and therapy? What if the patient asks to be referred for such therapy?

Discussion

Dr. Lowe, Dr. Sand and their critics may find guidance in the principles and rules of the American Academy of Ophthalmology Code of Ethics. In the Code of Ethics, the first concern is always the welfare of the patient. This implies ethical delivery of competent services to a patient who still desires those services after full disclosure. The obligation of the collective profession is to ensure that services of its members are rendered within these limits, implying evaluation and control of aberrant practitioners in order to determine what indeed is competent, as effective as possible, and in the best interests of the patient.

A generation of new technologies can arise as the result of many motives: frustration with the failure of current treatments, desire for fame, tenure, or the urge to find a gimmick with which to gain a market advantage over colleagues, among others. The new technologies that result from these motives may be worthy or not. Even if worthy, the new technologies may be used to exploit a vulnerable public. The motive that forces technological change is not of primary importance. It is important, however, that changes in traditional therapy be thoroughly evaluated before they are marketed to the public. Until that time, honesty requires that the value of the procedure be considered *uncertain*, and such must be understood by the patient and by the physician/innovator.

As mentioned above, the American Academy of Ophthalmology Code of Ethics offers guidance. Rule #3, governing clinical experiments and investigative procedures, as well as Rules #12 and #13, governing communications to colleagues and the public, must prevail. These rules require that we already know by common sense that others involved understand that the value of the technology is under investigation and not yet proven. Under these rules, one might legitimately advertise for subjects in a study to evaluate efficacy, but the requirements of informed consent might be difficult to satisfy. Code of Ethics Rule #3 states: "Use of clinical trials or investigative procedures shall be approved by adequate review mechanisms. Clinical trials and investigative procedures are those conducted to develop adequate information on which to base prognostic or therapeutic decisions or to determine etiology or pathogenesis, in circumstances in which insufficient information exists. Appropriate informed consent for these procedures must recognize their special nature and ramifications." American Academy of Ophthalmology Code of Ethics Rule #12 states: "Communications to colleagues must be accurate and truthful." Finally, Rule #13 states: "Communications to the public must be accurate. They must not convey false, untrue, deceptive, or misleading information through statements. Communications must not appeal to an individual's anxiety in an excessive or unfair way; and they must not create unjustified expectations of results."

The colleagues of an aberrant practitioner have an obligation to evaluate the therapy and the practitioner under the rules cited above. Scientific progress demands that nontraditional ideas be challenged and tested. The obligation is not only to exclude poor ideas and technologies, but to confirm and embrace good ones. The physician is also part of the therapeutic regimen and must be evaluated, along with his or her tools. A patient who asks

about a new therapy or an aberrant practice deserves unbiased, honest communication from the physician.

Again, the controlling interest of all involved in the profession is the *welfare of the patient*. Individuals and groups of physicians who keep that principle foremost will come to the best decision for the public and, therefore, for the profession.

COLLEGIALITY
Collegiality refers to the responsibilities of physicians to one another and to their profession, as well as the obligations of the collective profession to its individual members. Collegiality promotes constructive interaction of physicians and helps the profession define and maintain performance standards. An underlying objective of collegiality is to ensure the provision of a high quality of medical care.

Those who wish to call themselves a member of a particular group, such as a member of the medical profession, must abide by the rules of that group. With regard to the medical profession, the rules include both technical and behavioral requirements and knowledge both in the science and art of medicine. To learn these rules, and for these rules to remain appropriate, physicians must have close and continuing relationships with their colleagues and with their profession. When the relationships are lost or never develop, physicians make decisions on the basis of their own perceptions and precepts, which may or may not be consistent with those of their profession.

Case #4
Dr. Locale refers a patient to Dr. Ivory for help in the management of a postoperative surgical complication. The patient is a 40-year-old man who had a trabeculectomy performed one week earlier. According to a note from Dr. Locale, the patient's anterior chamber was very shallow on the first postoperative day, but no other problems were apparent. The day before the referral, the chamber became still shallower and now appears to be flat in all areas and the vision has declined. Dr. Locale's note requests Dr. Ivory's evaluation of the patient to assist Dr. Locale in determining how she should proceed with the patient.

Dr. Ivory examines the patient and concludes that surgery was properly performed. The chamber is completely flat, and Dr. Ivory believes that reformation of the anterior chamber is the next appropriate step. He advises the patient in this regard and turns to pick up the phone to convey this information to Dr. Locale. At that point, the patient says, "Dr. Ivory, I know you said that Dr. Locale did not make any mistakes, but she did send me to you for your opinion, and that shows that you must know more and are more experienced in these cases than she is. I would like you to do the next surgery." Dr. Ivory is concerned because Dr. Locale's note specifically requests a consultation and makes no mention of Dr. Ivory's proceeding with surgery or any other treatment.

Thought Questions
A. What responsibilities does the consulting physician have to the patient, to the referring physician, and to society?

B. What could the referring physician have done to prevent the problems that developed?

C. What does organized medicine need to do to decrease the likelihood that physicians will damage patients and the profession and vice versa?

Discussion
This case describes a common dilemma for a consulting physician. Dr. Ivory's primary responsibility is to the patient, but he also has obligations to himself, to the community, to the referring physician, and to the medical profession. Dr. Ivory must balance the patient's right of autonomy against his own ethical obligation of beneficence, that is, doing what is in the best interest of the patient. Although a competent patient has the right to reject recommended treatment, so, too, the physician has the right to decline compliance with a patient's request that he or she does not believe is in the patient's best interests, particularly when other ethical

obligations are involved, as in this case. The consulting physician may believe that the appropriate resolution in the present situation requires placing a greater weight on the principles of beneficence and collegiality than on the principle of autonomy.

By taking this patient from Dr. Locale, Dr. Ivory may indirectly cast doubts on Dr. Locale's competence although there appears to be no indication that the present case was handled other than competently. In other words, Dr. Ivory may abrogate his responsibilities to himself, his community, and his colleagues by complying with this patient's perceptions of his own self-interest. Ultimately, such compliance would be neither in the patient's nor the physician's best interests.

An appropriate next step, then, is for Dr. Ivory to explain to the patient in more detail that he found no indication that Dr. Locale's treatment was improper, and that the referral was not an unfavorable comment on Dr. Locale's competence; rather, request for consultation was an appropriate action, which he, Dr. Ivory, frequently took himself. Additionally, the operating surgeon, Dr. Locale, knew the details of the surgical procedure better than he as a consulting physician and was in a better position to perform the reoperation. It was in the patient's best interest to return to the referring doctor, Dr. Locale, for continuing care.

If at the end of the discussion, the patient still insists on having the next surgery performed by Dr. Ivory, Dr. Ivory must proceed very carefully. One approach would be for Dr. Ivory to explain that, although sympathetic to the patient's concerns, he did not believe them justified, that he considered Dr. Locale to be the most appropriate surgeon to continue the treatment.

In most cases, when a consulting physician reassures the anxious referred patient that the referring doctor has in fact performed competently and insists that it is in the patient's best interest to return to the referring doctor, that recommendation is accepted by the patient.

How could the uncomfortable situation described above have been avoided? Quite remarkably, most patients are *not* well informed as to why they are being referred. A comment such as "I want you to see Dr. Ivory," is often all that is said. Frequently, the patient arrives at the consultant's office without a prior call or an explanatory note. Not surprisingly, this type of referral leads to confusion and even resentment. It does not respect either patient autonomy or collegiality. It does not promote good patient care or good relationships.

It is appropriate to consider some comments regarding collegiality from other codes of ethics. The Hippocratic Oath states that the physician will "keep pure and holy both my life and my art." It is interesting and important to note the use of the word "art." The World Medical Association's Declaration of Geneva states, " . . . I will give to my teachers the respect and gratitude which is their due; I will maintain by all the means in my power, the honor and noble traditions of the medical profession; my colleagues will be my brothers." The World Medical Association's International Code of Medical Ethics requires that "a doctor ought to behave to his colleagues as he would have them behave to him." The Islamic Code of Medical Ethics is the most complete statement and should be read in its entirety. Included are the following comments: " . . . the brotherhood of physicians has that noblest of missions: to help one another in piety and charity. Theirs is the shared responsibility for the health of the nation and so the duty to help one another in providing the best care they can. The physician therefore should uphold the honor of his brother both in his presence and in his absence, and advise or help him when asked."

RELATED RESOURCES

For additional information related to subject matter addressed in this course, we suggest investigating the following:

- American Academy of Ophthalmology, Code of Ethics
- American Medical Association, Principles of Medical Ethics
- World Medical Association, The International Code of Medical Ethics and the Declaration of Geneva
- The Hippocratic Oath
- Advertising Directives

TEST
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Directions: To receive CME credit, please print and complete both pages of the test and course evaluation forms below, and submit them to the Clinical Education Division of the Academy by fax (415.561.8533) or mail (P.O. Box 7424, San Francisco, CA 94123). CME credit is available to all users of this educational activity.

Test Question: Colleagues of an innovative practitioner have a responsibility to evaluate both the therapy and the practitioner under the rules of ethics.

Please write a response indicating whether you agree or disagree with the above statement, and include your reasons.

Evaluation: Please indicate your agreement with the following statements about this course.

1. This online ethics course met its stated objectives.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

2. The topic area was comprehensively covered.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

3. The information presented in this course will be useful in my practice.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

4. The option of downloading and printing the course material is important.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

5. CME credit was an important reason for taking this online course.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

6. I would recommend this online course to others.

   Strongly Agree 1 2 3 4 5 Strongly Disagree

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